UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

ELI LILLY AND COMPANY, Plaintiff, v. PIVOTAL PEPTIDES, LLC, Defendant.	CASE NO. 2:24-cv-1719 **COMPLAINT** JURY TRIAL DEMANDED

1. Plaintiff Eli Lilly and Company ("Lilly") brings this action to protect Washington consumers from unstudied and unapproved drugs that are not intended for human use. Defendant Pivotal Peptides LLC ("Defendant") is engaging in a deliberate scheme to mislead consumers and illegally sell chemicals that it intends for humans to inject into their bodies—without prescriptions or the supervision of licensed medical professionals. These chemicals are illicit knockoffs of Lilly's FDA-approved medicines. In a reckless pursuit of personal profit and at the expense of public safety, Defendant markets its supposed weight-loss products (tirzepatide powder) on one hand as being "For Research Use Only"—*i.e.*, *not* for use with humans—but at the same time sells all of the necessary tools for personal injection and even provides specific dosing instructions. And at no point during the purchase process does Defendant require a valid prescription or even a medical consultation as is required for legitimate medicines. Indeed, Defendant is not licensed as a pharmacy or dispensary.

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2. Defendant knows this practice is unlawful and dangerous because Lilly sent its principals a letter stating so. In response, Defendant purported to close its website for maintenance, but then undertook a scheme to operate with "a lower profile." Defendant quickly reached out to its customers with instructions on how to purchase the product outside of its website using a codename, explaining: "**If a favorite product (starting with T) was your go-to, that name can't be used in any correspondence with me or listed on my price sheet anymore. Therefore, I need another identifier and decided (for now) to call this peptide '11mg.'**" These latest efforts attempting to disguise its illegal actions are another example of Defendant's reckless disregard for the law and patient safety.

3. Lilly institutes this action to protect patients from Defendant's dangerous, deceptive, and unlawful practices that violate Washington's laws and the public interest.

I. THE PARTIES

4. Plaintiff Lilly is an Indiana corporation with its principal place of business in Indianapolis, Indiana. Accordingly, Lilly is a citizen of Indiana.

5. Defendant Pivotal Peptides is a Washington limited liability company with its principal place of business in Lynnwood, Washington (Snohomish County). On information and belief, Defendant has two members: (1) Elizabeth Gately, a resident of Edmonds, Washington, and citizen of Washington; and (2) Hannah Swayne, a resident of Edmonds, Washington, and citizen of Washington. Accordingly, Defendant is a citizen of Washington.

II. JURISDICTION AND VENUE

6. The Court has subject matter jurisdiction over the causes of action pleaded herein pursuant to 28 U.S.C. § 1332 because the parties are diverse and the amount in controversy exceeds $75,000.

7. This Court has personal jurisdiction over Defendant as a citizen of this State. Further, Defendant: (1) transacts business in Washington; (2) maintains substantial contacts in Washington; and (3) committed violations of Washington law, in whole or part within the State of Washington. This action arises out of and relates to Defendant's contacts with this forum.

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8. Defendant purposefully availed itself of the privilege of doing business within this State, including within this County, and derived financial gain from doing so. These continuous, systematic, business contacts—including the tortious acts described herein—are such that Defendant should reasonably have anticipated being brought into this Court.

9. Venue is proper in this district and division pursuant to 28 U.S.C. § 1391 because Defendant operates and conducts business in this district and division. This is the district in which the Defendant resides as well as the district where all or part of the actions giving rise to Lilly's claim arose, namely the false and deceptive advertising of Defendants' products. Specifically, Defendant transacts business in this district and has an office for the transaction of business here.

III. FACTUAL ALLEGATIONS

A. Lilly's FDA-Approved Tirzepatide Injectable Medicines

10. Lilly is an international medicine company and pharmaceutical manufacturer. Throughout its nearly 150-year existence, Lilly has pioneered countless life-changing discoveries. Today, Lilly's medicines help tens of millions of patients across the globe, including in Washington.

11. Lilly manufactures its medicines under strict controls in state-of-the-art facilities, which employ thousands of highly specialized personnel to ensure that Lilly's medicines meet its—and global regulators'—rigorous quality and safety standards. Manufacturing active pharmaceutical ingredients, or API, and then transforming that API into medicine is a complex, methodical, and science-based process. Lilly follows Current Good Manufacturing Practices ("CGMP") across the design, monitoring, and control of manufacturing processes and facilities—from establishing robust quality management systems to obtaining quality raw materials and detecting and investigating product quality deviations. Each step—from chemical synthesis of the API to formulation, device assembly, and packaging—requires extensive testing and controls and specialized equipment.

12. Lilly is also subject to—and encourages—FDA oversight and compliance obligations, including routine regulatory inspections, adverse event reporting obligations, and

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post-market surveillance and studies. The same is true for other global regulators across the world. Additionally, Lilly's medicines must be, and always are, accompanied by important and highly regulated labels, instructions, and warnings, which themselves are approved by FDA.

B. MOUNJARO® and ZEPBOUND®

13. Using its experience and expertise, Lilly developed MOUNJARO® and ZEPBOUND®, which were approved by FDA for sale to the public in 2022 and 2023, respectively. Today, Lilly manufactures, markets, and sells MOUNJARO® and ZEPBOUND® throughout Washington and the United States.

14. Both MOUNJARO® and ZEPBOUND® contain tirzepatide as their API, which targets both GIP and GLP-1 hormone receptors.

15. Specifically, MOUNJARO® is designed to improve glycemic control in adults with type 2 diabetes mellitus (in addition to diet and exercise). As FDA has noted, "[d]espite the availability of many medications to treat diabetes, many patients do not achieve the recommended blood sugar goals."[1] MOUNJARO® targets this problem. When used as directed, MOUNJARO® has been clinically proven to improve blood sugar control more effectively than other diabetes therapies.

16. ZEPBOUND® is designed to help the millions of American adults with obesity or who are overweight and have weight-related medical problems. As FDA has noted, ZEPBOUND® "addresses an unmet medical need" by targeting "chronic weight management (weight reduction and maintenance)" through a new method of hormone receptor activation.[2] Accordingly, FDA has indicated ZEPBOUND® for adults with obesity (BMI of 30 kg/m2 or greater) or those who are overweight (BMI ≥ 27 kg/m2 or greater) and also have at least one additional weight-related condition, such as hypertension (high blood pressure), dyslipidemia

[1] https://web.archive.org/web/20221028212253/https://www.fda.gov/news-events/press-announcements/fda-approves-novel-dual-targeted-treatment-type-2-diabetes (archived FDA MOUNJARO® approval press announcement).

[2] https://www.fda.gov/news-events/press-announcements/fda-approves-new-medication-chronic-weight-management (FDA ZEPBOUND® approval press announcement).

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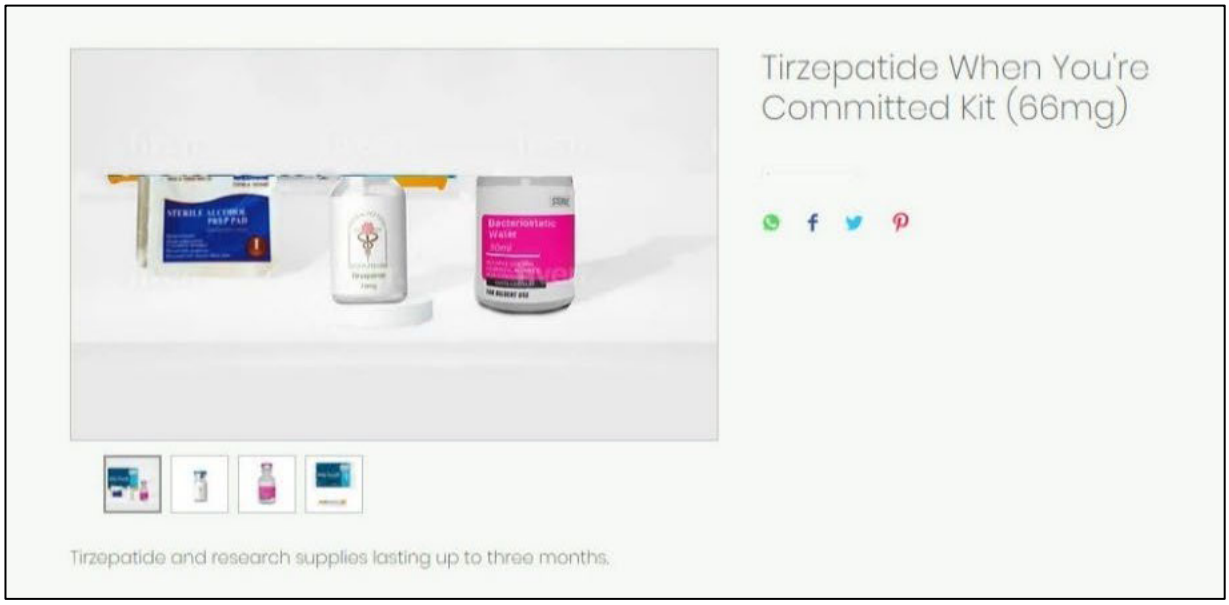
(high cholesterol or fats in blood), type 2 diabetes mellitus, obstructive sleep apnea, or cardiovascular disease.

17. Lilly exclusively owns the intellectual property rights related to MOUNJARO® and ZEPBOUND® and is the only lawful supplier of those medicines, which require a prescription from a licensed medical professional.

C. Defendant's Unlawful Scheme to Sell Prescription Drugs

18. Earlier this year, Lilly discovered that Defendant was marketing a tirzepatide drug online, which it referred to as a "Tirzepatide When You're Committed Kit."



19. The tirzepatide within Defendant's kit comes in "lyophilized," or freeze-dried, form. It is sold as a white powder in a vial.

20. Defendant's kit, which it sells for $720, purports to include all of the materials allegedly necessary to turn the powdered tirzepatide into a liquid solution that the user can inject subcutaneously (*i.e.,* under the skin) with a syringe. This includes bacteriostatic (or sterile) water, alcohol pads, and syringes necessary to reconstitute the powder and administer it.

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- **(6) Pivotal Peptides Tirzepatide 11mg Lyophilized Powder vials**
- **(3) Dial Pharmaceuticals Bacteriostatic Water 30ml vials**
- **(3) MHC Medical Products Easy Touch U-100 Insulin Syringes bags (10 syringes each)**
- **(32) Dealmed Sterile Alcohol Prep Pads**
- **(1) business card**
- **A 2-page Tirzepatide "information sheet"**
- **Paperwork for the order**

21. In selling these products, Defendant has created an outlet for Washingtonians (and others throughout the country and the world) to inject themselves with an unapproved, self-prepared drug, thus exposing people to unknown and potentially serious risks.

22. For instance, Defendant does not require a prescription to purchase its drug product. Instead, anyone with a credit card can purchase the drug at any time—regardless of age, risk profile, medical history, or medical need.

23. Indeed, Defendant never even inquires about the consumer purchasing its product: Defendant's customers may be children, people turned away by doctors because they are seeking the product for cosmetic weight loss, or other individuals whose medical history or profile would not support a tirzepatide prescription.

24. To dupe consumers into buying its drug product, Defendant has claimed that it "sells the highest pharma-grade peptides" and "best products available." Those messages have appeared in an advertisement featuring people measuring their waists—*i.e.,* boasting of weight loss:

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25. Defendant's claim to selling "pharma-grade" peptides is misleading and deceptive. The term "pharma-grade" conveys that the drug product is suitable for human consumption when, in reality, it is not.

26. Defendant also previously stated on its website that "With Pivotal Peptides we strengthen our bodies, nourish our skin and enhance our vitality, as we improve the quality of our lives"—again suggesting that the products are intended for human use.

27. Despite these representations, the tirzepatide product that Defendant ships is labeled "For Research Use Only," reflecting Defendant's knowledge (or reckless indifference to the fact) that the product is *not* safe for human consumption.

28. Defendant also stated elsewhere that its product was "DESIGNATED BY THE FDA AS A RESEARCH CHEMICAL FOR LAB RESEARCH AND VETERINARY PURPOSES ONLY."

29. Defendant has also made other claims to induce consumers to purchase and inject themselves with its product, including with business cards stating: "Peptides Can Be Life-Changing," "Starter and 'When You're Committed' Kits Available," "Pharma-grade Weight loss and Anti-aging Peptides," and "US Lab Tested with 99%+ Purity Guaranteed."

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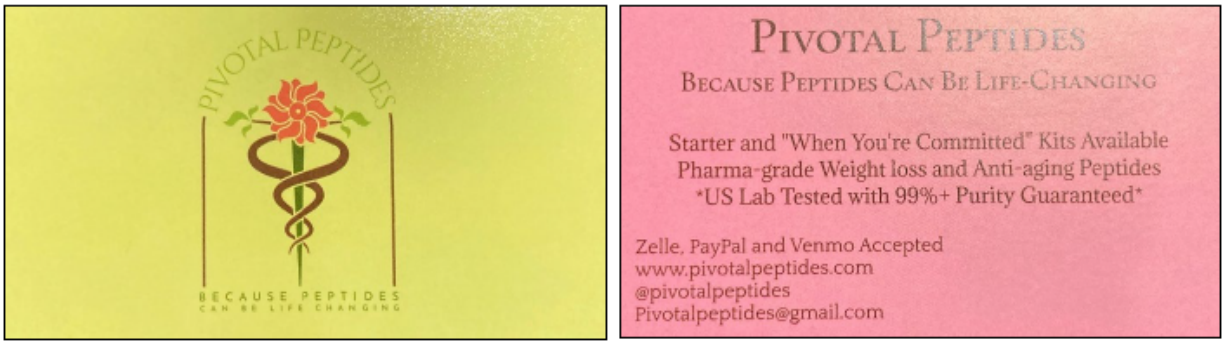

30. Defendant goes on to instruct consumers in an information sheet accompanying the "kit" on how to inject the untested and unapproved chemical into their bodies. Specifically, the information sheet provides:

> [A] common protocol [that] may be of interest to you [for preparing the powder for injection]:
>
> 1. First disinfect the work surface and wash hands …
>
> 2. Insert the 30-gauge syringe needle into the center of the bacteriostatic water and draw 100 units (1mL) into the syringe.
>
> 3. Pull the needle out and then gently inject the same water into the 10mg peptide vial, aiming for the side wall to "reconstitute" the powder….
>
> 4. Slowly roll vial in between the palm of hands until the powder is dissolved.
>
> 5. Draw 25 units for 2.5 mg, 50 units for 5 mg, 75 units for 7.5 mg, and 100 units for 10 mg dosages. The therapeutic dose for most weight loss is 15mg weekly.
>
> 6. Subcutaneous injections: Use an alcohol pad to disinfect the injection "pin" spot. Pinch fat found on stomach, thighs, hips between two fingers, hold while you use the other hand to inject the solution into the pinched subcutaneous fat. If you have help, you can also use the area on back of your arm….
>
> 7. It cannot be stressed enough that using fresh bacteriostatic water to reconstitute peptides is <u>essential</u>.

31. Defendant also plays on consumers' desires for fast results. Although Defendant's information sheet notes "Staying on as low a dose as possible if losing weight is a

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good idea for some people," it also encourages patients to increase their dosage. Specifically, the sheet instructs patients: "Bottom line is don't waste time sticking to a dose that is too weak! Increasing doses is cheaper overall than taking a lower amount over a longer period of time. That is a well-documented fact."

32. Despite the fact that pharmaceutical products (like MOUNJARO® and ZEPBOUND®) require a valid prescription from a healthcare provider, Defendant illegally sells its products without a prescription.

33. Defendant likewise expressly encourages patients to increase their dosage even though Defendant's customers are not purchasing the drug product as patients under the supervision of a medical professional.

34. Nowhere in Defendant's promotional materials does it warn about risks associated with its products (risks about which Defendant is likely aware given the lack of testing in humans), adverse events, or misuse by overdosing, underdosing, or increasing dosage too quickly, apart from a brief mention in the information sheet that "rush[ing] the amount of or frequency of doses … may increase risks of experiencing more severe negative side effects." Otherwise, Defendant provides no information of what those side effects are and instead instructs patients to "become well-informed of any risks and benefits associated with tirzepatide usage."

35. Defendant's business practices are unlawful, unfair, and deceptive under the laws of the State of Washington.

D. Defendant Knows Its Practices Are Unlawful and Dangerous Yet Continues to Covertly Sell Its Products

36. Defendant is aware that its conduct is unlawful, yet it continues to disregard the law and patient safety.

37. On July 12, 2024, Lilly sent Defendant a letter by regular mail and email (addressed to Defendant's registered agent and apparent principal Elizabeth Gately) explaining, in pertinent part:

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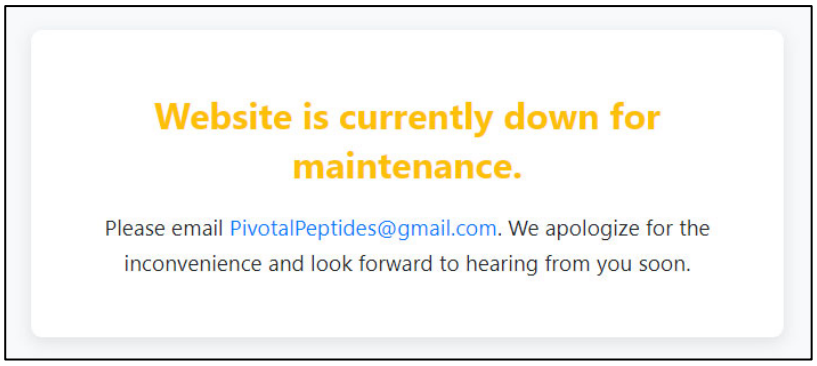
> Pivotal Peptides is selling research-grade "Tirzepatide" that poses serious risks to the American public. Research-grade product has not been purified to pharmaceutical-grade levels and is not approved for or appropriate for human use. Nonetheless, you are actively promoting and/or selling research-grade tirzepatide for the purpose of human consumption, as evidenced by your sales and/or promotional practices.

38. Lilly demanded that Defendant cease-and-desist from its unlawful conduct, including by stopping its promotion and sale of tirzepatide products.

39. Defendant never responded to Lilly's letter.

40. Instead, Defendant changed its website to state merely that the "Website is currently down for maintenance," and invited visitors to "please email" Defendant's Gmail address (PivotalPeptides@gmail.com), noting that it "look[ed] forward to hearing from [visitors] soon."



41. Notwithstanding that the website is "down for maintenance," Defendant did not stop selling its products. Rather, Defendant merely moved its operations to sell via email, Instagram, and word of mouth.

42. On or around July 22, 2024—ten days after Lilly sent Defendant a cease-and-desist letter—Gately sent an email to customers acknowledging that "Pivotalpeptides.com is no longer active," and explaining that they "needed a lower profile" because of "pharma pressure getting greater and close monitoring."

43. In the same email, Gately confirmed that Defendant was still in business, announcing: "Good News" that "Pivotal Peptides … is still in business!"

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44. Fully aware that its actions are illegal, Defendant instructed customers in coded (but obvious) language that: "**If a favorite product (starting with T) was your go-to, that name can't be used in any correspondence with me or listed on my price sheet anymore. Therefore, I need another identifier and decided (for now) to call this peptide '11mg.'**" The letter went on to state that the code-named product "is Pivotal Peptide's [sic] bestseller," and "it is the only T size available from PP right now except by special order." At the end of the email, Defendant reiterated: **"Remember to order '11 mg' with the latest price to identify the product you want, if applicable, and no longer use T in our communication."**

45. Defendant attached an Excel file titled "Prices for July 2024.xlsx" to its email in which it continued to offer its tirzepatide "kit"—the name of which Defendant has since changed to "11mg When You Are Committed Three Months Kit." The renamed "kit" continues to include bacteriostatic water, syringes, and alcohol pads.

46. Contrary to Defendant's purported disclaimer that its tirzepatide product is for research use only, the price list denotes that it *is* intended for human consumption. Specifically, the Excel states: "Not for human consumption with the exception of those noted with an asterick [sic]." The Excel then denotes all of the "11 mg" products with an asterisk, indicating those products *are* "for human consumption."

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Pivotalpeptides.com website is no longer active. Same great products and excellent customer service. NEW CUSTOMERS BY REFERRAL ONLY. If new to Pivotal Peptides, please provide the name of your referral when placing your order.

Free 2-5 day shipping with purchases over $250. Otherwise $8. Fed Ex Overnight shipping upon request.

Peptides sold here are for Research and Veterinary purposes only. Not for human consumption with the exception of those noted with an asterick. You are solely responsible for the use of these products. Please complete your own research prior to purchasing.

INSTRUCTION IS NOT AVAILABLE. PLEASE DO NOT ASK. Include your name, address, email, telephone number and indicate method of payment you will use when ordering. Thank you!

Products	Venmo price- use pivotalpeptides@gmail.com	Save up to 10% and more purchasing with Zelle and Paypal "Friends and Family " only - use @pivotalpeptides
Bacteriostatic water 30mL	$ 8.00	$ 7.00
10 count package of 30 gauge syringes	$ 4.00	$ 3.00
Bacteriostatic Water 30mL plus package of 10 syringes	$ 12.00	$ 10.00
***Eye Lash and Brow Serum**-apply to inner upper and		

Semaglutide 5mg	$ 75.00	$ 65.00	
Semaglutide 2mg x 2 each	$ 70.00	$ 60.00	
Semaglutide 2mg Starter Kit (one month)	$ 50.00	$ 45.00	
Semaglutide 10mg	$ 145.00	$ 125.00	
Semaglutide When You're Committed 3 Month Kit (14mg plus bacteriostatic water, syringes and alcohol pads)	$ 230.00	$ 200.00	
Retatrutide 12mg	$ 160.00	$ 140.00	
Retatrutide 12mg Starter kit	$ 170.00	$ 145.00	
Cargrilintide 5mg	$ 130.00	$ 115.00	
*11mg	$130 ea (2 for $250, 4 for $460)	$120 each (2 for $230, 4 for $440)	preorder of other sizes may be available
When You're Committed Three Month Kit (*66mg plus bacteriostatic water, syringes and alcohol pads)	$ 720.00	$ 650.00	
*11mg Starter Kit	$ 145.00	$ 130.00	
Box of 10 vials of "11mg"	$ 1,080.00	$ 970.00	
Mazdutide 9mg	$ 140.00	$ 120.00	
Mazdutide 3mg	$ 60.00	$ 40.00	
CJC-1295 without DAC 5mg	$ 38.00	$ 34.00	
Sermorelin 2mg	$ 30.00	$ 28.00	
Bpc-157 15mg	$ 65.00	$ 55.00	
Ipramorelin 5mg	$ 33.00	$ 30.00	
GHK-CU 100mg	$ 48.00	$ 43.00	

47. In sum, Defendant has engaged and continues to engage in unlawful, unfair, and deceptive business practices in violation of Washington law that endangers the safety of consumers in Washington and elsewhere. Tirzepatide is among many other pharmaceutical ingredients Defendant offers, evidencing a broad and sweeping operation that endangers patients across Washington state and elsewhere.

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48. Defendant has also violated Washington law through the unlicensed sale of drugs without a lawful prescription.

49. Defendant's unlawful, unfair, and deceitful conduct has exposed Washingtonians and consumers nationwide to serious health risks in violation of Washington laws and public interests, including the protection of patient, public, and consumer safety.

50. Defendant's unlawful and deceitful conduct also undermines the name, goodwill, and reputation that Lilly has invested heavily in developing its tirzepatide medicines. In particular, Defendant's litany of false and misleading statements undermines and cheapens the unique trust consumers place in Lilly and its products based on Lilly's years-long efforts to prove its medicines safe and effective, and to obtain FDA approvals for its tirzepatide medications, MOUNJARO® and ZEPBOUND®.

FIRST CAUSE OF ACTION

Unfair Business Practices pursuant to the Washington Consumer Protection Act, RCW § 19.86.010 et seq.

51. Lilly repeats and realleges each and every allegation above as if fully set forth herein.

52. The Washington Consumer Protection Act ("WCPA") broadly prohibits "unfair or deceptive acts or practices in the conduct of any trade or commerce." RCW § 19.86.010.

53. Both Defendant and Lilly are "persons" as defined by RCW § 19.86.010.

54. Defendant committed the acts complained of herein in the course of "trade" or "commerce" within the meaning of RCW § 19.86.010.

55. Defendant has violated the WCPA by, at a minimum, taking the following actions:

a. Selling tirzepatide product without a valid prescription from a licensed medical professional, in violation of Washington's laws and public interests.

b. Making materially false and misleading statements regarding its tirzepatide product's safety, quality, and regulatory status, which

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influenced and will continue to influence consumers' purchasing decisions and threaten their health and safety.

c. Making materially false and misleading statements regarding its tirzepatide product's intended use by marketing them for human consumption when they are not.

56. Defendant's actions have the tendency to deceive reasonable consumers, who have relied or likely will rely on Defendant's false statements in making their purchasing decisions.

57. As a direct and proximate result of Defendant's false and deceptive campaign, Defendant has put the safety of Washingtonians (and other American consumers) at risk with its illegal products. Additionally, Lilly has suffered and will continue to suffer significant injury by the loss of goodwill associated with Lilly's MOUNJARO® and ZEPBOUND® tirzepatide medicines.

58. As a direct and proximate result of Defendant's false and deceptive campaign, Defendant has unfairly benefitted and profited from sales it made as a result of goodwill associated with Lilly's MOUNJARO® and ZEPBOUND® tirzepatide medicines.

59. Defendant is liable to Lilly for damages in amounts to be proven at trial, including attorneys' fees, costs, and treble damages, as well as any other remedies the Court may deem appropriate under RCW § 19.86.090.

SECOND CAUSE OF ACTION

Unfair Competition pursuant to the Washington Consumer Protection Act, RCW § 19.86.010 et seq.

60. Lilly repeats and realleges each and every allegation above as if fully set forth herein.

61. The Washington Consumer Protection Act ("WCPA") broadly prohibits "[u]nfair methods of competition … in the conduct of any trade or commerce." RCW § 19.86.010.

62. Both Defendant and Lilly are "persons" as defined by RCW § 19.86.010.

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63. Defendant committed the acts complained of herein in the course of "trade" or "commerce" within the meaning of RCW § 19.86.010.

64. Defendant has violated the WCPA, at a minimum by taking the following actions:

a. Selling tirzepatide product without a valid prescription from a licensed medical professional, in violation of Washington's laws and public interests.

b. Misleading consumers that its tirzepatide product is suitable for human use.

65. As a direct and proximate result of Defendant's unlawful campaign, Defendant has put the safety of Washingtonians (and other American consumers) at risk with its illegal products. Additionally, Lilly has suffered and will continue to suffer significant injury by the loss of goodwill associated with Lilly's MOUNJARO® and ZEPBOUND® tirzepatide medicines.

66. As a direct and proximate result of Defendant's unlawful campaign, Defendant has unfairly benefitted and profited from sales it made as a result of goodwill associated with Lilly's MOUNJARO® and ZEPBOUND® tirzepatide medicines.

67. Defendant is liable to Lilly for damages in amounts to be proven at trial, including attorneys' fees, costs, and treble damages, as well as any other remedies the Court may deem appropriate under RCW § 19.86.090.

IV. PRAYER FOR RELIEF

WHEREFORE, Lilly prays that this Court enter judgment in its favor on its claim for relief set forth above and award it relief including, but not limited to, the following:

A. a determination and declaration that Defendant has violated the Washington Consumer Protection Act;

B. judgment in favor of Lilly and against Defendant for damages (including attorneys' fees, treble damages, and civil penalties) in a specific amount to be proven at trial;

C. injunctive relief in accordance with RCW § 19.86.010 *et seq.*, to the effect that Defendant, its affiliates, successors, transferees, assignees, and the officers, directors, partners,

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agents, and employees thereof, and all other persons acting or claiming to act on its behalf or in concert with them, be enjoined and restrained from in any manner continuing, maintaining or renewing the conduct alleged herein in violation of Washington law;

D. an order providing that Lilly:

1. be awarded restitution, damages (including but not limited to treble damages, attorneys fees, and penalties as permitted by RCW § 19.86.010 *et seq*.,) and all other legal and equitable relief to which Lilly may be entitled;

2. be awarded pre- and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of the initial Complaint in this action;

3. recover its costs of this action; and

4. be awarded such other further relief as the case may require and the Court may deem just and proper under the circumstances.

V. JURY DEMAND

Lilly demands trial by jury on all issues so triable.

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DATED: October 21, 2024

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By: *s/ John S. Devlin*
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By: *s/ Daniel R. Miller*
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